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510(k) SUMMARY for K113452

Ascendx Spine, Inc.'s Acu-Cut Vertebral Augmentation System

FEB 17 2012

Submitter

Ascendx Spine, Inc.
7079 University Blvd
Winter Park FL 32792

Phone: (321) 280-4800
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Contact Person: Teresa Cherry

Date Prepared: July 16, 2012 (revised)

Name of Device

Acu-Cut Vertebral Augmentation System

Classification Name

Vertebroplasty, Cement, Bone

Predicate Devices

Medtronic USA, Inc.'s Arcuate Vertebral Augmentation System (K070527)

Intended Use / Indications for Use

The Acu-Cut Vertebral Augmentation System is indicated for the treatment of painful pathological fractures of the vertebral body. Vertebral compression fractures may result from osteoporosis, benign lesions and/or malignant lesions such as metastatic cancers and myeloma. It is intended to be used in combination with Ascendx Cement.

Technological Characteristics

The Acu-Cut Vertebral Augmentation System consists of:

- the Acu-Cut Cutting Instrument
- 2 Cannulas
- 1 Tri-Point Tip Trocar
- 1 Bevel Tip Trocar
- 1 Hand Drill

- 5 Cement Delivery Tubes with Plungers
- A previously FDA cleared bone cement.

Performance Data

Comprehensive bench and clinical testing of the Acu-Cut Vertebral Augmentation System was conducted. Testing included:

- Bench testing for the Acu-Cut Cutting Instrument
  - Cutting torque testing in osteoporotic vertebrae and sawbones
  - Tensile strength testing of Cutting Instrument band
  - Cutting Instrument flex cable weld strength testing
- Bench testing for the Trocars, Cannulas, Hand Drills and Cement Delivery Devices
  - Insertion testing
  - Trocar Handle Strength Testing
  - Torque and Tensile Strength Testing
  - Cement Delivery Instrument Testing
  - Removal Force Testing
- Sterilization Validation
- Packaging and Shipping Validations
- Biocompatibility Testing
- Clinical Testing – Ascendx VCF Repair System IDE study
- Accelerated and Real Time Aging Testing

The testing demonstrated that the System conforms to its design specifications. The testing also demonstrated the Acu-Cut System's ability to mechanically withstand insertion and deployment within a vertebral body. In all instances, the Acu-Cut System functioned as intended.

Substantial Equivalence

The Acu-Cut Vertebral Augmentation System is substantially equivalent to the predicate device. The Acu-Cut Vertebral Augmentation System has the same intended uses and indications as the predicate Arcuate Vertebral Augmentation System. Both systems include a cutting device that is used to create a cavity by cutting cancellous bone within the vertebral body. Both systems include Class I instruments for gaining access to the vertebral body and for delivering previously cleared bone cement. The technological characteristics and principles of operation of the Acu-Cut System are also similar to the predicate. The minor technological differences between the Acu-Cut Vertebral Augmentation System and its predicate device, e.g., with respect to dimensions, etc., raise no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 17 2012

Ascendx Spine, Incorporated
% Hogan LovellsUS LLP
Ms. Janice M. Hogan
Regulatory Counsel
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K113452
Trade/Device Name: Acu-Cut Vertebral Augmentation System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, KIH
Dated: November 21, 2011
Received: November 21, 2011

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin P. Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113452

Device Name: Acu-Cut Vertebral Augmentation System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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